NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MONOSOL RX, LLC, Plaintiff, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., MEDA PHARMACEUTICALS INC., and AVEVA DRUG DELIVERY SYSTEMS, INC. Defendants.	Civ. No 10-5695 (FLW/DEA) OPINION

WOLFSON, U.S. DISTRICT JUDGE:

This matter comes before the Court on a motion for summary judgment filed by Defendants Biodelivery Sciences International, Inc., Meda Pharmaceuticals Inc., and Aveva Drug Delivery Systems, Inc. (collectively, "Defendants") on the Amended Complaint filed by Plaintiff MonoSol Rx., LLC ("MonoSol," or "Plaintiff"). In the Amended Complaint, Plaintiff asserts patent infringement claims against Defendants on three patents: (1) United States Patent No. 7,824,588 ("the'588 patent); (2) United States Patent No. 7,425,292 ("the '292 patent"); and (3) United States Patent No. 7,357,891 ("the '891 patent"). Following ex parte reexamination of all three patents by the U.S. Patent and Trademark Office ("PTO"), Defendants move for summary judgment on all claims, asserting the defense of intervening rights, and more specifically, absolute intervening rights.

For the following reasons, Defendants' motion is granted.

I. Background

At issue in this case are various inventions for making ingestible, pharmaceutical films. The following facts are undisputed unless otherwise indicated.

a. History of the Litigation and Requesting Reexamination of Patents-in-Suit

On November 2, 2010, MonoSol filed this action against BDSI, its strategic partner, Meda, and its contract manufacturer, Aveva, for alleged infringement of the '588 patent by BDSI's Onsolis® products. Defs.' Statement of Undisputed Material Facts ("Defs.' Stmt. of Facts") ¶ 1; Dkt. 1. The '588 patent is a "method of making self-supporting therapeutic active-containing film," *see* '588 Patent Cover Page, and, according to Plaintiff's Complaint, "BDSI, MEDA, and Aveva (collectively, "Defendants") make, use, offer to sell, and/or sell certain pharmaceutical films under the Onsolis™ name." Compl. ¶ 12. BDSI requested that the PTO reexamine the '588 patent on September 12, 2011.[1] Defs.' Stmt. of Facts ¶ 2; Dkt. 46-3. On November 10, 2011, the PTO granted BDSI's request to reexamine the '588 patent. Defs.' Stmt. of Facts ¶ 4; *see also* Nov. 10, 2011 Order Granting Request For '588 Reexamination.

On September 26, 2011, MonoSol amended its Complaint to assert infringement of the '891 patent and the '292 patent. Defs.' Stmt. of Facts ¶ 5; Dkt. 47. The '891 patent is a "process for

[1] BDSI and Aveva filed a motion to stay the litigation on September 16, 2011, in light of BDSI's reexamination request. Defs.' Stmt. of Facts ¶ 3; Dkt. 46.

For background, "[w]hen a patent claim is reexamined by the PTO, there are three possible outcomes—it can be cancelled as unpatentable, it can be confirmed as originally written, or it can be modified." *Ever Win Int'l Corp. v. Radioshack Corp.*, 902 F. Supp. 2d 503, 505 (D. Del. 2012). 35 U.S.C. § 305 governs the conduct of reexamination proceedings. "In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter." *Id.*

making an ingestible film,"[2] and the '292 patent is "a "thin film with non-self-aggregating uniform heterogeneity and drug delivery systems made therefrom."[3] '891 Patent Cover page; '292 Patent Cover Page. On January 20, 2012, BDSI requested that the PTO reexamine both patents. Defs.' Stmt. of Facts ¶ 6; Dkt. 60-5, Dkt. 60-6. The PTO instituted the reexamination of the '292 patent on February 16, 2012,[4] and the reexamination of the '891 patent on March 1, 2012.[5], Defs.' Stmt.

[2] "Desirably, the films disintegrate in water and may be formed by a controlled drying process, or other process that maintains the required uniformity of the film. Desirably, the films may be exposed to temperatures above that which the active components typically degrade without concern for loss of the desired activity." *See* '891 Patent Cover Page. The '891 patent issued on April 15, 2008. Defs.' Stmt. of Facts ¶ 41; *see also* '891 Patent Cover Page.

[3] The '292 patent "relates to the film products and methods of their preparation that demonstrate a non-self-aggregating uniform heterogeneity. Desirably[,] the films disintegrate in water and may be formed by a controlled drying process, or other process that maintains the required uniformity of the film." *See* '292 Patent Cover Page. The '292 patent issued on September 16, 2008. Defs.' Stmt. of Facts ¶ 14; *see also* '292 Patent Cover Page.

[4] Specifically, in its February 16, 2012 order granting the request for ex parte reexamination, the PTO found that prior art raised "substantial new questions" of patentability as to all of the '292 patent's claims. Feb. 16, 2012 Order Granting Request for Ex Parte Reexamination. Further, in a separate "office action" filed that same day, the PTO found that "[c]laims 1–20 are rejected under 35 U.S.C. 103(a) as being unpatentable" over two patents, referred to as Chen and Strobush. Feb. 16, 2012 Office Action in Ex Parte Reexamination of '292 Patent, at 4; *see also infra* notes 7–8 and accompanying text. "Claim 21 [was] rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Strobush as applied to claims 1–20 above, and further in view of" a patent known as Mehra. Feb. 16, 2012 Office Action in Ex Parte Reexamination of '292 Patent, at 11. Finally, "Claim 22 [was] rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Strobush as applied to claims 1–20 above, and further in view of" a patent known as Dohner. *Id.* at 12.

[5] Specifically, in its March 12, 2012 order granting the request for ex parte reexamination, the PTO found that prior art raised "substantial new questions" of patentability as to the all of the '891 patent's claims. March 12, 2012 Order Granting Request for Ex Parte Reexamination. Further, in a separate "office action" filed that same day, the PTO found that "[c]laims 1–6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable" over Chen and Strobush. March 12, 2012 Office Action in Ex Parte Reexamination of '891 Patent, at 4. Further, "[c]laims 7 and 9 [were] rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Strobush as applied to claims 1–6 and 8 above, and further in view of" a patent known as Staab. *Id.* at 11.

of Facts ¶ 7; *see also* Feb. 16, 2012 Order Granting Request For '292 Reexamination; March 1, 2012 Order Granting Request For '891 Reexamination.[6]

b. The '588 Patent Reexamination – Patent Cancelled

On January 23, 2013, the PTO issued a right of appeal notice, rejecting all claims of the '588 patent. Defs.' Stmt. of Facts ¶ 10; *see also* Jan. 23, 2013 Right of Appeal Notice. On February 22, 2013, MonoSol appealed the rejection to the Patent Trial and Appeal Board (the "PTAB"). Defs.' Stmt. of Facts ¶ 11; *see also* Feb. 22, 2013 Notice of Appeal. On April 17, 2014, the PTAB confirmed the rejection. Defs.' Stmt. of Facts ¶ 12; *see also* Apr. 14, 2014 PTAB Decision on Appeal at p. 22. On August 5, 2014, the PTO issued a Certificate of Reexamination cancelling all claims of the '588 patent. Defs.' Stmt. of Facts ¶ 13; *see also* Aug. 5, 2014 Ex Parte Reexamination Certificate for '588 Patent at Col. 1.

c. The '292 Patent Reexamination – Patent Modified

On July 3, 2012, the PTO issued a reexamination certificate for the '292 patent. July 3, 2012 '292 Patent Ex Parte Reexamination Certificate. The original '292 patent contained 22 claims. *See* '292 Patent. Upon reexamination, the PTO found that (1) claims 1, 10, 13–15, and 17–22 are patentable as amended, (2) claims 2–9, 11, 12, and 16, dependent on an amended claim, are patentable, and (3) new claims 23–55 are added and determined to be patentable. *Id.* Col. 1.

The original language of each of independent claims 1, 10, 13–15, and 17–22 of the '292 patent is different, but, following reexamination, each of those claims contains the following four additions: (1) "including said active component," (2) "active component comprising," (3) "by

[6] On January 23, 2012, BDSI and Aveva renewed their motion to stay the litigation pending resolution of the three reexamination proceedings. Defs.' Stmt. of Facts ¶ 8; Dkt. 60. The Court granted the renewed motion to stay on March 7, 2012, staying the action in its entirety. Defs.' Stmt. of Facts ¶ 9; Dkt. 64. On January 23, 2015, the Court vacated the stay and restored the action to the active docket, after which Defendants filed the instant motion for summary judgment.

rapidly increasing the viscosity of said film upon initiation of drying," and (4) "whereby said compositional uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component." Defs.' Stmt. of Facts ¶ 16; *compare* '292 Patent at 26:11-32:13 *with* '292 Patent Ex Parte Reexamination Certificate at 1:25–6:67. By way of example, Claim 1 of the reexamined '292 patent reads as follows, with the added language underlined:

> 1. A process for making a self-supporting, edible film having a substantially uniform distribution of components comprising:
>
> (a) mixing an edible water-soluble polymer component, water and an active component comprising drug particles to form an edible matrix with a compositionally uniform distribution of said components <u>including said active component</u>;
>
> (b) deaerating said matrix by mixing;
>
> (c) forming a wet film from said deaerated matrix by coating or coating the film;
>
> (d) providing a surface having top and bottom sides;
>
> (e) feeding said film onto said top side of said surface; and
>
> (f) drying said film within about 10 minutes or fewer, wherein said drying step further comprises:
>
> (i) <u>rapidly</u> [typo corrected – had read rapidiy] forming a visco-elastic film having <u>said active component</u> comprising drug particles uniformly distributed throughout <u>by rapidly increasing the viscosity of said film upon initiation of drying</u> within about the first 4.0 minutes by applying hot air currents at temperatures of about 60° C. to about 100° C. to said bottom side of said surface with substantially no top air flow to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components <u>including said active component</u>; and
>
> (ii) further drying said visco-elastic film to form a self supporting edible film having <u>active component comprising</u> drug particles uniformly distributed throughout, <u>whereby said compositional uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component</u>.

Defs.' Stmt. of Facts ¶ 17; July 3, 2012 Ex Parte Reexamination Certificate for '292 Patent at 1:25–1:57.

Defendants state that "[d]uring reexamination of the '292 patent, MonoSol attempted to distinguish the claims from prior art including Chen[7] et al., WO 00/42992 (July 27, 2000) ("Chen") and Strobush[8] et al., U.S. Patent No. 5,881,476 (March 16, 1999) ("Strobush")."[9] Defs.' Stmt. of Facts ¶ 18 (citing Apr. 6, 2012 Summary of the Interview, pp. 2–5) (discussing claims relative to Chen and Strobush)). Defendants further state that "[i]n an interview, the Examiner and MonoSol discussed, in reference to claims of the '292 patent, the uniformity of active content disclosed in the '292 patent compared to the appearance of uniformity as disclosed in Chen and Strobush."[10]

[7] Chen, a patent titled "Compositions and methods for mucosal delivery," is a "dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat-forming film, such film including an effective dose of active agent. In the dosage unit sildenafil citrate, nicotine, hydromorphone, oxybutynin or estradiol are used as active agents." *See* Chen Patent Cover Page.

[8] Strobush, a patent titled "Apparatus and method for drying a coating on a susbtrate employing multiple drying subzones," is "an apparatus and method for evaporating a coating solvent from a coating on a first substrate surface of a substrate and for minimizing the formation of mottle as the coating solvent is evaporating. A drying oven includes an enclosure having an inlet and an outlet and defining a first drying zone. A plurality of drying subzones are within the first drying zone. At least two of the plurality of drying subzones employ different and controllable drying conditions. Physical barriers are not required to create the plurality of drying subzones." *See* Strobush Patent Cover Page.

[9] Plaintiff disputes this statement, instead stating that "[d]uring reexamination of the '292 patent, MonoSol attempted to distinguish the original claim language from prior art. At the time of the interview, on March 30, 2012, Plaintiff had not yet amended the claims." Pl.'s Response to Defs.' Stmt. of Facts ¶ 18 (citing Apr. 6, 2012 Reply to Non-Final Office Action)).

[10] Plaintiff does not dispute that the uniformity of the invention in the '292 patent and the uniformity of the compositions disclosed in the prior art was discussed during the March 30, 2012 interview. However, Plaintiff disputes the generalization "in reference to claims of the '292 patent." According to Plaintiff, "[t]he claims are not referenced or cited in the summary at all." Pl.'s Response to Defs.' Stmt. of Facts ¶ 19 (citing March 30, 2012 Ex Parte Reexamination Interview Summary)). Plaintiff also disputes that "[t]he Examiner required the patentee to add the phrase 'including said active component' twice in each amended independent claim in order to distinguish the alleged invention over prior art." Pl.'s Response to Defs.' Stmt. of Facts (quoting Defs.' Br. at 10, citing ¶¶19–22). Plaintiff further disputes that "MonoSol used this phrase [including said active component] to distinguish the alleged invention from [Chen and Strobush]." Pl.'s Response to Defs.' Stmt. of Facts (quoting Defs.' Br. at 11 (citing ¶ 18–20)).

Defs.' Stmt. of Facts ¶ 19 (citing Apr. 30, 2012 Ex Parte Reexamination Interview Summary) ("The degree of uniformity of the instant film, particularly with respect to drug content was discussed relative to Chen and Strobush . . . Patent Owner will consider adding claim language to specify the uniformity.")). Defendants further state that "MonoSol performed several experiments to demonstrate that the alleged invention of the '292 patent–the uniform distribution of active content–was different from Chen's glossy films and from Strobush's unmottled films, both of which were uniform in appearance."[11] Defs.' Stmt. of Facts ¶ 20 (citing Apr. 6, 2012 Summary of the Interview, pp. 2–5) ("The patentee distinguished the type of uniformity of the present invention, which is directed to uniformity of active content, from the specific visual uniformities described in the Chen and Strobush references.")). Defendants further state that "[f]ollowing communications with the Examiner, MonoSol added the phrase "including said active component"

[11] Plaintiff does not dispute that the uniformity of the invention in the '292 patent and the uniformity of the compositions disclosed in the prior art were discussed during the March 30, 2012 interview. However,

> Plaintiff disputes the characterization of "the alleged invention of the '292 patent" as "the uniform distribution of active content" because that is only one part of the claimed invention. Plaintiff also disputes that "[t]he Examiner required the patentee to add the phrase 'including said active component' twice in each amended independent claim in order to distinguish the alleged invention over prior art" and that "the Examiner found that this amendment further limits the claim to cover processes that result in films with uniform distribution of active components, and not uniform distribution only of other ingredients that result in visual uniformity as described in the prior art." Defs.' Br. at 10–11 (citing SOF ¶ 19–22). There is absolutely no support for Defendants' contention that the Examiner "required" this amendment to be made to distinguish over the prior art or "found that this amendment further limits the claim." Defs.' Br. 10–11. Defendants also do not point to a single instance where the Examiner found the "including said active component" language to be limiting.
>
> Plaintiff further disputes that "MonoSol used this phrase [including said active component] to distinguish the alleged invention from [Chen and Strobush]." Defs.' Br. at 11 (citing ¶¶ 18–20). Nowhere is the phrase "including said active component" mentioned in any argument made by the patentee.

Pl.'s Response to Defs.' Stmt. of Facts ¶ 20.

twice in each amended independent claim of the '292 patent in the reexamination." Defs.' Stmt. of Facts ¶ 21 (citing July 3, 2012 Ex Parte Reexamination Certificate for '292 Patent at e.g., 1:32 and 1:50)). Defendants characterize the Examiner's Reasons for Patentability of the claims of the '292 patent as containing the amendment "including said active component" and noting that neither Chen nor Strobush teaches uniformity of active component.[12] Defs.' Stmt. of Facts ¶ 22 (citing May 11, 2012 Reasons For Patentability)). Defendants further state that "[i]n an initial communication in the reexamination of the '292 patent, the Examiner pointed out that prior art – and Chen in particular – had previously disclosed drug particles."[13] Defs.' Stmt. of Facts ¶ 23 (citing Feb. 16, 2012 Order Granting Request For '292 Reexamination, pp. 6, 10)).

MonoSol submitted to the Examiner the results of experiments that purportedly demonstrated the '292 patent's invention uniformity of active content comprising particles, distinguishing the less uniform "glossy" and "unmottled" results of the processes of Chen and Strobush. Defs.' Stmt. of Facts ¶ 24 (citing Apr. 4, 2014 Smolenski Decl. at ¶¶ 5–9)). MonoSol added the phrase "active component comprising" twice in each amended independent claim of the '292 patent in the reexamination. Defs.' Stmt. of Facts ¶ 25 (citing July 3, 2012 Ex Parte

[12] Plaintiff does not dispute that the allowed claims of the '292 patent contained the phrase "including said active component." However, "Plaintiff disputes that the Examiner's statements that neither Chen nor Strobush teaches uniformity is tied to the amendment. In his reasons for allowance, the Examiner focused on elements of the claims that were never amended, and there is not a single mention of the phrase 'including said active component.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 22 (citing May 11, 2012 Reasons For Patentability).

[13] Plaintiff argues that "[t]he disclosure of 'drug particles' alone in the prior art was not relied on by the Examiner. The Order Granting Request for Reexamination actually states: 'Chen teaches a dosage unit including a water-soluble hydrocolloid, mucosal surface-coat-forming film, such film including an effective dose of an active agent . . . . The therapeutic agent can be in the form of colloidal particles or microencapsulated material which are dispersed in the film . . . .'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 23 (citing Feb. 16, 2012 Order Granting Request For '292 Reexamination, at 6)).

Reexamination Certificate for '292 Patent at e.g., 1:40 and 1:52). The Examiner noted in his Reasons For Patentability of the '292 patent that "Chen does not discuss compositional uniformity of an active component comprising drug particles." Defs.' Stmt. of Facts ¶ 26 (citing May 11, 2012 Reasons For Patentability). In response to the Examiner's comments regarding prior art, MonoSol reported on a series of experiments that allegedly distinguished the process of the '292 patent claims from Chen and Strobush. The experiments allegedly confirmed that through the Chen and Strobush processes, which do not have "the claimed rapid formation of the visco-elastic film, particularly at the initiation of the drying phase, a useful, uniform active-containing product is not achieved."[14] Defs.' Stmt. of Facts ¶ 27 (citing Apr. 6, 2012 Reply to Non-Final Office Action, at 39).

MonoSol advised the Examiner during reexamination of the '292 patent: "If one were to incorporate the drying process of Strobush into the teachings of Chen, one would arrive at a process that necessarily … slowly ramps up the temperature at which the wet film is dried. This is in direct contrast to the presently claimed invention [that] require[s] a rapid formation of a visco-elastic film as the drying is initiated so as to 'lock-in' the active component in place within the time and temperature ranges claimed. Thus, the combination of Strobush and Chen fails to arrive at the present invention." Defs.' Stmt. of Facts ¶ 28 (citing Apr. 6, 2012 Reply to Non-Final Office Action, pp. 36–37).

[14] Plaintiff disputes this statement insofar as "Defendants[] mischaracterize the experiments reported by the patentee as overcoming the prior art because of the limitation (and heading of this section): 'by rapidly increasing the viscosity of said film upon initiation of drying.' The limitation is not mentioned anywhere in the reply." Pl.'s Response to Defs.' Stmt. of Facts ¶ 27 (citing Apr. 6, 2012 Reply to Non-Final Office Action, p. 39)).

According to Defendants, "[d]uring an interview, the Examiner suggested that MonoSol add language to claims of the '292 patent concerning the rapid formation of the visco-elastic film to distinguish over prior art."[15] Defs.' Stmt. of Facts ¶ 29 (citing April 6, 2012 Summary of the Interview, pp. 4–5 ("[I]t was suggested by the Examiners that since the rapid formation of the visco-elastic film appeared to be important [in context of prior art], further claim language toward this feature may be helpful … [S]uch amendments appeared to distinguish over the combination of Chen and Strobush."). Defendants further state that "[a]fter adding the language suggested by the Examiner during the interview, MonoSol stated that the amended claim language of the '292 patent covered processes 'where rapid viscosity increase is achieved at the initial stage of drying' due to high temperatures."[16] Defs.' Stmt. of Facts ¶ 30 (citing Apr. 6, 2012 Reply to Non-Final Office Action, p. 30). Defendants further state that "[i]n his explanation of why the amended claims of the '292 patent were allowed, the Examiner stated that Chen does not describe the early drying

[15] According to Plaintiff, "Defendants mischaracterize Examiner's suggestion as necessary to distinguish over prior art, and Defendants' incorrectly use ellipses to connect two separate, unrelated sentences." Pl.'s Response to Defs.' Stmt. of Facts ¶ 29.

[16] According to Plaintiff, "[t]he Examiner suggested that the patentee's addition of claim language toward the feature of the 'rapid formation of the visco-elastic film' because it 'appeared to be important.' Apr. 6, 2012 Summary of the Interview, at 4–5. Patentee described that independent claims 1, 10, 13, 14, 15, 17, 18, 19, and 20 were amended in the patentee's April 6, 2012 amendment to 'clarify : . . . that the rapid formation of a visco-elastic film is achieved by 'by rapidly increasing the viscosity of said film upon initiation of drying.' Apr. 6, 2012 Reply to Non-Final Office Action, p. 24 (emphasis added). The patentee also stated: 'Further, the claims have been amended to clarify that the first step in the drying process is to rapidly form a visco-elastic film "by rapidly increasing the viscosity of the film upon initiation of drying." This clarifies that the rapid viscosity increase is achieved at the initial stage of drying, i.e., that the film is initially exposed to a temperature that rapidly increases its viscosity.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 30 (citing Apr. 6, 2012 Reply to Non-Final Office Action, p. 24).

stages and that the Chen process dries films more slowly than the claimed process."[17] Defs.' Stmt. of Facts ¶ 31 (citing May 11, 2012 Reasons for Patentability).

In response to the Examiner's rejections during reexamination of the'292 patent, on the basis of prior art, Defendants state that "MonoSol stated that Chen and Strobush 'fail to disclose the presently claimed uniformity, specifically achieving a uniformity of no more than 10% variance in active content between substantially equally sized unit doses of dried film.'"[18] Defs.' Stmt. of Facts ¶ 32 (citing Apr. 6, 2012 Reply to Non-Final Office Action, p. 36). Defendants further state that "[i]n an interview during reexamination of the '292 patent, the Examiner suggested the addition of language specifying the uniformity of active content required by the amended claims."[19] Defs.' Stmt. of Facts ¶ 33 (citing Apr. 6, 2012 Summary of the Interview, pp. 4–5) ("Examiners raised the issue of the definition of 'uniformity of content'. It was suggested by the Examiners to amend the claim to add 'uniformity of content per unit dose' of film as well as a

[17] Plaintiff argues that "Defendants' inaccurately paraphrase the Examiner's reasons for allowance. The Examiner distinguished Chen because it exemplified drying 'outside of the claimed temperature range.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 31 (citing May 11, 2012 Reasons for Patentability). "Further, the Examiner found that none of the prior art discussed 'compositional uniformity.' These original limitations are completely unrelated to the 'by rapidly increasing the viscosity of said film upon initiation of drying' amendment." Defs.' Stmt. of Facts ¶ 31 (citing May 11, 2012 Reasons for Patentability).

[18] Plaintiff argues that "[i]ndependent claims 1, 10, 13, 14, 15, 17, 18, 19, and 20 were amended in the patentee's April 6, 2012 amendment to 'clarify: . . . that the uniform distribution of active components is measured by "substantially equally sized individual unit doses which do not vary by more than 10% of active component."'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 32 (citing Apr. 6, 2012 Reply to Non-Final Office Action, p. 24) (emphasis added)). "In its remarks, the patentee argued that the prior art 'also fail[s] to disclose the presently claimed uniformity'— the same uniformity that was already inherent in the prior claims." Pl.'s Response to Defs.' Stmt. of Facts ¶ 32 (citing Apr. 6, 2012 Reply to Non-Final Office Action, p. 36).

[19] Plaintiffs argue that "Defendants inaccurately describe Examiner's suggestion and inaccurately use ellipses to connect two separate, unrelated sentences in the text." Pl.'s Response to Defs.' Stmt. of Facts ¶ 33.

maximum amount of variance of active content being no more than 10% or less of the targeted 100% Label Claim per unit dose . . . [S]uch amendments appeared to distinguish over the combination of Chen and Strobush.")).

Defendants further state that "MonoSol followed the Examiner's suggestion to add language specifying the uniformity of active content, but initially only for some of the independent claims of the '292 patent. The Examiner required MonoSol to amend Claims 21 and 22 of the '292 patent twice because MonoSol did not include the 10% uniformity limitation to distinguish Chen and Strobush in the first set of amendments to those claims."[20] Defs.' Stmt. of Facts ¶ 34 (citing Apr. 24, 2012 Supplemental Amendment and Remarks, pp. 11–12, 21) ("Claims 21–22 did not include a limitation regarding the measure of uniformity, and the Examiner requested the amendment be included.")). Next, Defendants state that "[a]fter MonoSol added the 10% uniformity limitation to all independent claims of the '292 patent, the Examiner stated in his Reasons For Patentability that neither Chen nor Strobush discloses or quantifies uniformity of active ingredient, noting 'Table 4 of Chen gives the grams per dosage film and density for Example 1 with standard deviation based on three or four measurements, but does not give compositional uniformity.'"[21] Defs.' Stmt. of Facts ¶ 35 (citing May 11, 2012 Reasons For Patentability).

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[20] Plaintiffs argue that "[t]he Examiner did not 'require' patentee to add this phrase to the independent claims to distinguish the invention over prior art. Rather, during an interview, '[i]t was suggested by the Examiners to amend the claim to add "uniformity of content per unit dose" of film as well as a maximum amount of variance of active content being no more than 10% or less of the targeted 100% Label Claim per unit dose.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 34 (citing Apr. 6, 2012 Summary of the Interview, pp. 4–5). Plaintiffs further argue that "[t]here is no indication that this suggestion was made to overcome the prior art." Pl.'s Response to Defs.' Stmt. of Facts ¶ 34.

[21] Plaintiff continues to object that "[i]ndependent claims 1, 10, 13, 14, 15, 17, 18, 19, and 20 were amended in the patentee's April 6, 2012 amendment to "clarify: . . . that the uniform distribution of active components is measured by 'substantially equally sized individual unit doses

According to Defendants, "[t]he dependent claims of the reexamined '292 patent are all new."[22] Defs.' Stmt. of Facts ¶ 36 ('292 Patent Ex Parte Reexamination Certificate at Cols. 7–8)). Specifically, "[t]he new dependent claims of the reexamined '292 patent have added language limiting the water content of the resulting film to 10% by weight and limiting the active component to the form of a solution, emulsion, or suspension." Defs.' Stmt. of Facts ¶ 37 (citing '292 Patent Ex Parte Reexamination Certificate at Cols. 7–8 (internal citations omitted); Feb. 24, 2012 Ex Parte Reexamination Interview Summary ("Patent Owner agreed to remove one of either "solution", "emulsion", "colloid" or "suspension" so that claims 57+ are further limiting.")). "Other new dependent claims of the '292 patent added limitations on the feeding step of the claimed process and on the coating or casting step of the process." Defs.' Stmt. of Facts ¶ 38 (citing '292 Patent Ex Parte Reexamination Certificate at cols. 7-8) (internal citations omitted). Plaintiff, however, disputes this characterization of the claims. Pl.'s Response to Defs.' Stmt. of Facts ¶ 37.

d. The '891 Patent Reexamination

The PTO issued a reexamination certificate for the '891 patent on August 21, 2012. Defs.' Stmt. of Facts ¶ 34. The original '891 patent contained 9 claims. *See* '891 Patent. Upon reexamination, the PTO found that (1) claims 1-9 were cancelled, and (2) independent claims 10–11 and dependent claims 12–28 were added. Defs.' Stmt. of Facts ¶ 53; *see also* '891 Patent Ex Parte Reexamination Certificate Col. 1.

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which do not vary by more than 10% of active component.'" Apr. 6, 2012 Reply to Non-Final Office Action, p. 24 (emphasis added).

[22] Plaintiff disputes this statement "to the extent that Defendants' characterization of the claims is inaccurate. The reexamined patent states: 'Claims 1, 10, 13–15 and 17–22 are determined to be patentable as amended. Claims 2-9, 11, 12 and 16 dependent on an amended claim, are determined to be patentable. New claims 23-35 are added and determined to be patentable.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 36 (citing '292 Patent).

The phrase "wherein said desired level is measured by substantially equally-sized individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active component" was included in independent claims 10 and 11 of the '891 patent during the course of reexamination, which otherwise track the language of cancelled claims 1 and 9. Defs.' Stmt. of Facts ¶ 46 (citing May 1, 2012 Reply By Patentee to Non-Final Office Action, pp. 19–20). By way of example, Claim 10 of the reexamined patent reads as follows, and tracks claim 1, with the additional language underlined:

> 10. A process for making an ingestible film having a substantially uniform distribution of components and a desired level of a pharmaceutical or biological active component, comprising the steps of:
>
> (a) combining a polymer component, water and a pharmaceutical or biological active component to form a matrix with a uniform distribution of said components;
>
> (b) forming a film from said matrix;
>
> (c) providing a conveyor surface having top and bottom sides;
>
> (d) feeding said film onto said top side of said surface; and
>
> (e) drying said film within about 10 minutes or fewer by applying hot air currents to said bottom side of said conveyor surface with substantially no hot air currents on the top side of said surface and exposing said film to a temperature above a degradation temperature of said pharmaceutical or biological active component, wherein said degradation temperature is 70° C. or higher,
>
> wherein said pharmaceutical or biological active component is maintained at said desired level, <u>wherein said desired level is measured by substantially equially-sized [sic] individual unit does which do not vary by more than 10% of said pharmaceutical or biological active component</u>.

'891 Patent Ex Parte Reexamination Certificate at claim 10; *see also* '891 Patent at claim 1.

In a summary of an interview with the Examiner during reexamination of the '891 patent, MonoSol stated, "The Patentee and Examiner discussed clarifying the 'desired level' of active in the claims as being measured by 'substantially equally-sized individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active component'. This language provides further definition to the language that is already present in the issued claim." Defs.' Stmt. of Facts ¶ 46 (citing May 1, 2012 Summary of the Interview at 3)). Further, Defendants state that

"[d]uring the reexamination of the '891 patent, MonoSol attempted to distinguish the claims from prior art including Chen and Strobush."[23] Defs.' Stmt. of Facts ¶ 44 (citing May 1, 2012 Summary of the Interview; May 1, 2012 Reply By Patentee to Non-Final Office Action).

According to Defendants, "

> [i]n its Office Action Reply during reexamination of the '891 patent dated the same day as the interview, MonoSol summarized, 'New claims 10 and 11 have been added, which track the language of claims 1 and 7, but further recite that the 'desired level' of active is measured by substantially equally-sized individual unit doses which do not vary by more than 10% of the pharmaceutical or biological active component. This clarifies that the active component is maintained in a known and useful amount, thereby controlling degradation to a workable and useable level, and clarifies that level in further detail … there is absolutely no disclosure of controlling such degradation to a desired level claimed [in Chen] . . . . [T]hese new independent claims are likewise allowable over the combination of Chen and Strobush.'"[24]

Defs.' Stmt. of Facts ¶ 47 (citing May 1, 2012 Reply By Patentee to Non-Final Office Action, at 19-20). Defendants further state that "[t]he new claims 10 and 11 of the '891 patent tracked the original claims 1 and 7, respectively, except that claims 10 and 11 had the added language

[23] According to Plaintiff, "[t]he patentee stated that 'these new independent claims are likewise allowable over the combination of Chen and Strobush,' using the same arguments for claims 10 and 11 as it did to argue that the original claims were allowable." Pl.'s Response to Defs.' Stmt. of Facts ¶ 44 (citing Christie Decl., Ex. R (May 1, 2012 Reply By Patentee to Non-Final Office Action, pp. 19–20)). "The word 'likewise' refers back to two sentences prior that 'Independent claim 1 is allowable over Chen and Strobush' in light of the arguments made on pp.17-20, none of which recite or depend upon the phrase "wherein said desired level is measured by substantially equally-sized individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active component" at issue here. Therefore, MonoSol disagrees that it attempted to distinguish the claims from prior art including Chen and Strobush." Pl.'s Response to Defs.' Stmt. of Facts ¶ 44.

[24] Plaintiff disputes this statement, arguing that "[u]nrelated phrases are linked through the improper use of the ellipses to make it seem as though the patentee had made statements regarding 'degradation to a desired level' with respect to the new claims. In fact, the same arguments were made with respect to both claims 1 and 7, the original claims, and claims 10 and 11. Pl.'s Response to Defs.' Stmt. of Facts ¶ 47 (citing May 1, 2012 Reply By Patentee to Non-Final Office Action, pp. 19–20).

specifying active content uniformity."[25] Defs.' Stmt. of Facts ¶ 48 (citing May 1, 2012 Reply By Patentee to Non-Final Office Action, at 19–20; '891 Patent at claims 1 and 7; '891 Patent Ex Parte Reexamination Certificate at claims 10 and 11). Defendants also state that "MonoSol did not cancel original claims 1 and 7 of the '891 patent in its first sets of amendments."[26] Defs.' Stmt. of Facts ¶ 49 (citing May 1, 2012 Reply By Patentee to Non-Final Office Action, at 9).

Defendants state that "[t]he Examiner ultimately required cancellation of the original claims 1 and 7 of the '891 patent, because claims 1 and 7 omitted the new limiting language requiring measurement by unit doses that do not vary by more than 10% of active component."[27] Defs.' Stmt. of Facts ¶ 50 (citing June 27, 2012 Fifth Supplemental Amendment and Response, p. 7;

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[25] Plaintiff argues that "[i]ndependent claims 10 and 11, added to the '891 patent during reexamination, mirrored claims 1 and 7, respectively and added the phrase 'wherein said desired level is measured by substantially equally-sized individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active component' to the end of the claim for clarification of the phrase 'substantially uniform distribution" in the preamble.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 48 (comparing the '891 patent with Christie Decl. Ex. D ('891 Ex Parte Reexamination Certificate)).

[26] Plaintiff disputes this statement, arguing that "[t]he patentee did cancel the claims in its Fifth Supplemental Amendment and Response, stating: 'Therefore, at the request of the Examiner and without any admission as to the propriety of the Examiner's rejection, claims 1-9, 12, 13, 16-19, 24, 38 and 39 are canceled.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 49 (citing June 27, 2012 Fifth Supplemental Amendment and Response, at 7).

[27] Plaintiff disputes this statement, arguing that "[t]he Examiner did not require cancellation of the claims. In its summary of the interview which led to the patentee choosing to cancel claims 1 and 7, the patentee stated that '[t]he applicant asserted that claims 1 and 7 are believed to be allowable over the prior art for reasons previously stated, however, to facilitate reexamination, the Applicant agreed to cancel claims 1 and 7 . . . .'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 50 (quoting June 27, 2012 Interview Summary)). "In the response in which the patentee canceled the claims, it stated: 'Therefore, at the request of the Examiner and without any admission as to the propriety of the Examiner's rejection, claims 1-9, 12, 13, 16–19, 24, 38 and 39 are canceled.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 50 (citing June 27, 2012 Fifth Supplemental Amendment and Response, at 7).

compare '891 Patent at claims 1 and 7 *with* '891 Patent Ex Parte Reexamination Certificate at claims 10 and 11)).

In his July 6, 2012 Reasons For Patentability of the '891 patent, the Examiner stated, "Chen does not discuss uniformity or pharmaceutical or biological active component in its doses. Table 4 of Chen gives the grams per dosage film and density for Example 1 with standard deviation based on three or four measurements, but does not give compositional uniformity," and that "Strobush provides no teaching with respect to compositional uniformity." Defs.' Stmt. of Facts ¶ 51 (quoting July 6, 2012 Reasons For Patentability). The PTO issued a reexamination certificate for the '891 patent on August 21, 2012. Defs.' Stmt. of Facts ¶ 52 (citing '891 Ex Parte Reexamination Certificate).

e. Status of Onsolis® Products

Defendants state that "[n]o original claim remains from any of the three patents that MonoSol has asserted against BDSI in this case."[28] Defs.' Stmt. of Facts ¶ 52 (citing '891 Patent Ex Parte Reexamination Certificate; '292 Patent Ex Parte Reexamination Certificate; and '588 Patent Ex Parte Reexamination Certificate). Defendants further state that "[n]one of the Defendants has imported into, or made, used, offered to sell or sold in the United States the accused Onsolis® product since 2011."[29] Defs.' Stmt. of Facts ¶ 55 (citing Finn Decl., at ¶¶ 3–6.) Finally, Defendants

[28] Plaintiff disputes this statement, arguing that "all claims of the '588 patent have been canceled. The USPTO issued reexamination certificates for the '292 patent and the '891 patent on July 3, 2012 and August 21, 2012, respectively, with claims that were substantially identical to the original claims." Pl.'s Response to Defs.' Stmt. of Facts ¶ 54 (internal citations omitted).

[29] Plaintiff does not directly dispute this statement, though it argues that "BDSI has officially admitted through a January 27, 2015 press release that it was 'preparing to make [a] submission" for Onsolis® to the FDA in the first quarter of 2015." Pl.'s Response to Defs.' Stmt. of Facts ¶ 55 (citing BDSI Press Release: Biodelivery Sciences Acquires North American Marketing Authorizations for Onsolis from Meda, January 27, 2015), available at http://bdsi.investorroom.com/2015-01-27-BioDelivery-Sciences-Acquires-North-American-

state that "Meda has not sold the accused Onsolis® product in the United States since March 29, 2011." Defs.' Stmt. of Facts ¶ 55 (citing Hostler Decl., at ¶ 5).

After the PTO issued its reexamination certificates as to all three patents at issue, and this Court lifted its stay on the proceedings pending the PTO's reexaminations, Defendants moved for summary judgment on Plaintiff's patent infringement claims, on the defense of intervening rights.

II. Standard of Review

A moving party is entitled to judgment as a matter of law where there is no genuine issue as to any material fact. *See* FED R. CIV. P. 56(c); *Celotex Corp. v. Catrett,* 477 U.S. 317, 323 (1986)); *Brooks v. Kyler,* 204 F.3d 102, 105 n.5 (3d Cir. 2000) (citing FED. R. CIV. P. 56(c)). The burden of demonstrating the absence of a genuine issue of material fact falls on the moving party. *See Taylor v. Phoenixville Sch. Dist.,* 184 F.3d 296, 305 (3d Cir. 1999). Once the moving party has satisfied this initial burden, the opposing party must identify "specific facts which demonstrate that there exists a genuine issue for trial." *Orson, Inc. v. Miramax Film Corp.,* 19 F.3d 1358, 1366 (3d Cir. 1996).

Not every issue of fact will be sufficient to defeat a motion for summary judgment; issues of fact are genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). Further, the nonmoving party cannot rest upon mere allegations; he must present actual evidence that creates a genuine issue of material fact. *See* FED. R. CIV. P 56(e); *Anderson,* 477 U.S. at 249. In conducting

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Marketing-Authorizations-for-ONSOLIS-from-Meda (last visited March 23, 2015)). "A product launch is imminent, as BDSI is in 'discussions with potential commercial partners' who will work with BDSI to 'bring Onsolis® back to the U.S. marketplace.'" Pl.'s Response to Defs.' Stmt. of Facts ¶ 55 (citing BDSI Press Release).

a review of the facts, the non-moving party is entitled to all reasonable inferences and the record is construed in the light most favorable to that party. *See Pollock v. Am. Tel. & Tel. Long Lines,* 794 F.2d 860, 864 (3d Cir. 1986). Accordingly, it is not the court's role to make findings of fact, but to analyze the facts presented and determine if a reasonable jury could return a verdict for the nonmoving party. *See Brooks,* 204 F.3d at 105 n.5 (citing *Anderson,* 477 U.S. at 249).

III. Discussion

Defendants move for summary judgment under the intervening rights doctrine, arguing that the reexamination proceedings for the ’292 and ’891 patents substantively changed the claims of the patents on which Plaintiff bases its infringement contentions. On that basis, Defendants contend that they are entitled to absolute intervening rights, precluding any award of damages for Defendants’ actions prior to the PTO’s issuances of the ’292 and ’891 reexamination certificates. Plaintiff counters by arguing that the ’292 and ’891 patent claims were not so substantively changed as to permit Defendants to assert intervening rights.

a. Intervening Rights

“The doctrine of intervening rights first developed as courts recognized that permitting substantive changes to the scope of patent claims through post-issuance procedures left the door open for gross injustice where a third party, having already begun to make, use, or sell a given article, finds its previously lawful activities rendered newly infringing under a modified patent.” *See Marine Polymer Technologies, Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1361–62 (Fed. Cir. 2012) (en banc) (internal quotation marks omitted). The concept of intervening rights was first codified with respect to reissued patents, and has since been extended to reexamined patents under 35 U.S.C. § 307(b), which provides:

> Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that

> specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.

35 U.S.C. § 307(b). Thus, only "amended" or "new" claims in a reexamined patent give rise to the defense of intervening rights. *Id.*; *see also Marine Polymer*, 672 F.3d at 1363.

As noted, patent law provides for two types of intervening rights: (1) "absolute intervening rights," which sever liability for an infringer for accused products that were made or used before the reexamination certificate issue; and (2) "equitable intervening rights," where a court, in its equitable discretion, may provide for a party to continue to engage in infringing activities—*e.g.*, to continue to make or use products—after the reexamination certification has issued if the accused infringer made substantial preparations for the infringing activities prior to the reexamination. *See* 35 U.S.C. §§ 252, 307; *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1339 (Fed. Cir. 2013). Here, Defendants make clear in their reply brief that they "base their motion solely on absolute intervening rights." Defs.' Reply Br. at 13. [30]

[30] In Defendants' motion for summary judgment and in their statement of material facts, Defendants state that they "have not made or sold the accused product . . . . since 2011, well before the issuance of the '292 and '891 patent reexamination certificates." Defs.' Br. at 23. In a footnote, Defendants argue that "[a]lleged infringers may be entitled to equitable intervening rights relating to products that were made or used after the reexamination if substantial preparations were made for them prior to reexamination." *Id.* at 23 n.8 (citing *Marine Polymer*, 672 F3d at 1361–62). While Defendants go on to state that, "[h]ere, the issue of equitable intervening rights is moot because there are no accused products that could potentially infringe MonoSol's reexamined patents," *id.*, in their proposed order, they request an order that "Plaintiff is not entitled to damages arising from its assertion of [the '891 patent] and [the '292 patent] against Defendants for the time period following the issuance of those patents' respective certificates of examination." *See* Proposed Order, at 2. Further, Plaintiff (1) construes Defendants' argument as one "for dismissal because there is no case or controversy," (2) reframes the argument as one for declaratory judgment on the issue of "whether Defendants have shown 'meaningful preparation' for making or using the product, even if they have not yet sold the product, and (#) argues that "BDSI has publicly stated through a press release that it is nearly ready to go back to market. Pl.'s Opp. at 30.

After determining that the claim upon which the intervening rights are premised is new or has been amended, *see Marine Polymer*, 672 F.3d at 1361–62, the Court must determine whether the accused product or activity infringes on a claim that remains "without substantive change" after the reexamination; if the claim has not been substantively changed, the doctrine of intervening rights does not apply. S*eattle Box Co. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 827–28 (Fed. Cir. 1984); *Bloom Eng'g Co. v. N. Am. Mfg. Co.*, 129 F.3d 1247, 1250 (Fed. Cir. 1997) ("Unless a claim granted or confirmed upon reexamination is identical to an original claim, the patent cannot be enforced against infringing activity that occurred before issuance of the reexamination certificate."); *see also Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 975–77 (Fed. Cir. 1986) (explaining the relationship between §§ 252 and 307(b) and holding that "identical," as used in § 252, means "without substantive change" under § 307(b)).

Here, there is no dispute among the parties that Defendants' intervening rights defense is based upon claims that have been amended or added in the '292 and '891 reexamination proceedings.[31]

In their reply brief, Defendants argue that they base their motion solely on absolute intervening rights and that "[t]he proposed order that MonoSol cites is directed to dismissal of MonoSol's claims for the time period after reexamination certificates issued because no accused product has been made or sold since before those certificates issued." Defs.' Reply Br. at 13 (emphasis removed). Further, Defendants argue that "MonoSol now seeks an advisory opinion from this Court on whether the amended claims of the '292 and '891 patents would be infringed if, in the future, Defendants are (1) able to obtain FDA approval to make a fentanyl product and (2) then reintroduce that still-to-be approved product on the marketplace." Defs.' Reply Br. at 14.

The Court will solely consider on this motion the issue of whether Defendants are entitled to assert the defense of absolute intervening rights during the period before the '292 and '891 reexamination certificates were issued. Thus, the Court declines to issue any orders about potential infringement that may occur after reexamination had concluded.

[31] The parties quibble over whether the '891 patent's claims 10 and 11 are actually "new" claims, or whether they should be considered amended versions of the patent's original claims 1 and 9. The PTO cancelled the '891 patent's nine original claims upon reexamination; however, the parties do not dispute that claims 10 and 11 track the language of the cancelled claims 1 and 9, with the phrase "wherein said desired level is measured by substantially equally-sized individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active

Thus, I proceed to determining whether these claims were amended without substantive change, thereby precluding application of the defense.

"To determine whether a claim change is substantive it is necessary to analyze the claims of the original and the reexamined patents in light of the particular facts, including the prior art, the prosecution history, other claims, and any other pertinent information." *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) ("*Laitram IV*") (internal quotation marks omitted). Like with claim construction, these reexamined claims "are not to be interpreted by adding limitations appearing only in the specification." *Electro Med. Sys. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994). Overall, the focus is on whether the amended claims are of a "different scope" than the original claims. *Laitram IVv*, 163 F.3d at 1348.

Claims define the scope of the inventor's right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction is designed to determine the correct claim scope, a determination exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995) *aff'd*, 517 U.S. 370 (1996). This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman*, 52 F.3d at 986 ("The focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean"); *Phillips*, 415 F.3d at 1312–13.

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component" added to the end of both claims. The Court finds Plaintiff's argument that "new claims can relate back to the original patent if the test [for substantial identicality] under § 252 is met." Pl.'s Opp. Br. at 22, to be well taken, and will analyze whether the above additional language constitutes a substantial change over the original claims 1 and 9.

In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification and prosecution history) and extrinsic evidence (e.g., expert reports, testimony and anything else). *Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999). In interpreting the disputed terms, it is well settled that the court should look first to the intrinsic evidence. *Vitronics Corp.*, 90 F.3d at 1362. Generally, words in patent claims are given their ordinary meaning as understood by one of ordinary skill in the art at the priority date of the patent application. *Dow Chem.*, 257 F.3d at 1372; *K–2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362 (Fed. Cir. 1999). The claims must be construed objectively in the context of both the particular claim and the entire patent because "the claims themselves provide substantial guidance as to the meaning of particular claim terms," and claim terms are normally used consistently throughout the patent. *Phillips*, 415 F.3d at 1313–14.

Moreover, courts are instructed to look to the specification, which is a written description of the invention. "[C]laims 'must be read in view of the specification, of which they are a part.'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979). Indeed, the specification is perhaps "the single best guide to the meaning of a claim term" due to its statutory requirements of being in "full, clear, concise, and exact terms." *Phillips*, 415 F.3d at 1316; see 35 U.S.C. § 112. "[It] acts as a dictionary when it expressly" or implicitly defines terms used in the claims. *Markman*, 52 F.3d at 979. In this way, the specification can "set the scope and outer boundary" of the claim. *On Demand Mach. Corp. v. Ingram Industries, Inc.*, 442 F.3d.1331, 1340 (Fed. Cir. 2006). Conversely, "limitations appearing in the specification will not be read into the claim." *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1348 (Fed. Cir. 2008).[32]

[32] As a threshold matter, the parties do not dispute that I may rule on Defendants' motion for summary judgment without holding a *Markman* hearing or the parties proceeding through discovery; rather, both parties agree that I may decide the issue based upon the original and

a. '292 Patent

Here, the parties agree that each of the independent claims 1, 10, 13–15, and 17–22 of the '292 patent was amended to include the following claim limitations: (1) "including said active component," (2) "active component comprising," (3) "by rapidly increasing the viscosity of said film upon initiation of drying," and (4) "whereby said compositional uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component." Defendants contend that these changes are substantive and that they narrowed the scope of the original claims; Plaintiff argues that these changes merely clarified limitations that were always present in the claims. If the Court concludes that one of these changes is substantial, thereby altering the scope of the claim, the remaining amendments need not be addressed. *See Laitram IV*, 163 F.3d at 1345 ("The added limitations generally address three aspects of the disclosed invention: speed, type quality, and direction of movement. Because our conclusion regarding claim identicality may be based on the type quality amendment alone, we limit our analysis to that limitation."); *see also Bloom Eng'g Co. v. N. Am. Mfg. Co.*, 129 F.3d 1247, 1251 (Fed. Cir. 1997) (affirming summary judgment on the basis of intervening rights despite disagreeing with the district court on whether one of the two claim amendments at issue was a substantive change). For that reason, I begin my analysis of the reexamined '292 patent by examining whether the amendment regarding uniform composition—specifically, the addition of the phrase "whereby said compositional uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component"—constitutes a substantial change.

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amended claim language, as well as the prosecution history. *See, e.g.*, *Eberle v. Harris*, No. CIV.A.03-5809 (FLW), 2010 WL 6281563, at *5 (D.N.J. June 30, 2010); *see also Laitram IV*, 163 F.3d at 1347.

a. "whereby said compositional uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component"

First, the prosecution history reveals that the amendment in question had the effect of distinguishing the '292 patent from prior art. Claims 1–20 were initially cancelled because they were unpatentable over prior art. According to the PTO, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the drying method taught by Strobush to the film formation method disclosed by Chen to achieve uniformity in density of the active component in Chen's dried film." Specifically, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to dry Chen's film in, for example, three zones as in Strobush and determine the appropriate parameters, including time, for each zone, so as to dry the film such that it is virtually mottle proof in the first zone and then remove remaining water in the subsequent two zones." Feb. 16, 2012 Office Action in Ex Parte Reexamination, at 9–10.[33] In March 30, 2012, an interview was conducted between the Examiners, the inventor, and a MonoSol Representative, which was summarized by Daniel A. Scola, Jr., attorney for the Patentee. Apr. 6, 2012 Summary of the Interview. Under the summary heading "Discussion of the Cited References, Chen and Strobush," it was reported that "[a] brief discussion of both the Chen and

[33] As to Claim 21, the PTO found that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide anti-foaming agent to Chen's matrix so as to prevent foaming of the composition during mixing." *Id.* at 12. As to Claim 22, the PTO found that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared Chen's premix in one mixing vessel, then transferred it to another vessel of a cooler temperature, and then stirred in heat sensitive drug ingredients because such is conventional processing in the art and so as to avoid degradation of the heat sensitive drug." *Id.* at 13. Further, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have used reverse roll coating in place of solvent casting for applying Chen's matrix to the polyester backing belt because the substitution of one well known method (i.e.d, solvent casting) for another (i.e., reverse roll coating) would have been within the level or ordinary skill in the art." *Id.* at 13–14.

Strobush references then ensued. Chen was discussed with relation to its general teaching of drug-containing film, made in accordance with a general temperature range . . . and for a nine . . . minute drying time." *Id.* at 3. As to Strobush,

> [t]he Patentee agreed with the Examiner's statement that the key to Strobush's process is a low hΔt (small rate of heat exchange) in order for his process to reach his only objective: a mottle-free film. Whereas Strobush requires a very small change in heat transfer rate over time, the inventive process [in question] requires a larger change in heat transfer rate starting from the initiation of the drying process, in order to rapidly form the visco-elastic film and "lock-in" place the uniformly distributed active.

Id. "The Patentee then explained the results of comparative testing that was performed . . . to determine whether a process using the Chen/Strobush teachings would result in uniformity of content of active per unit dose as compared to the same formulation made in accordance with the present invention." *Id.* at 4. Three comparative samples were prepared, using (1) the inventive process in question, (2) low heat and top and bottom drying (consistent with Strobush's teaching) and (3) high heat and high velocity top drying. Jan. 20, 2012 Myers Decl., at 3. While "[e]ach of the samples appeared visually uniform and mottle free . . . the Patentee . . . stressed that the two comparative samples were non-uniform in content," as opposed to the result of the samples prepared using the inventive process. Specifically, according to a declaration of Garry Myers, the named inventor of the '292 patent, the comparative testing showed that by using the inventive process at issue, the active content ranges from 102.7% to 107.3% of the targeted label claim. By using a drying method consistent with the teaching in Strobush, the active content ranges from 92.8% to 117.7% of the targeted label claim. By using a high heat, high velocity drying method, the active content ranges from 95.5% to 117.7% of the targeted label claim. Jan. 20, 2012 Myers Decl., at 4. Thus, the inventive process' achievement of less than 10% variation in active content per dose is a critical point of distinction over prior art.

Still within the summary section titled "Discussion of the Cited References, Chen and Strobush," the Examiners addressed the suggested amended language as follows:

> The claims were then addressed and it was suggested by the Examiners that since the rapid formation of the visco-elastic film appeared to be important, further claim language towards this feature may be helpful. The Patentee then discussed potential claim amendments relating to the rapid visco-elasticity formation, beginning at the initial portion of the drying process. In addition, the Examiners raised the issue of the definition of "uniformity of content." It was suggested by the Examiners to amend the claim to add "uniformity of content per unit dose" of film as well as a maximum amount of variance of active content being no more that 10% or less of the targeted 100% Label Claim per unit dose. The Patentee then suggested claim language to address these comments, and *it was indicated by the Examiners that such amendments appeared to distinguish over the combination of Chen and Strobush*.

Apr. 6, 2012 Summary of the Interview, at 4 (emphasis added).

This interview summary excerpt indicates that the amendment to the claim language in the '292 patent relating to the uniform distribution of the active component had the effect of distinguishing the '292 patent from the Chen and Strobush combination by focusing the claims upon the achievement of a uniform distribution of drug particles over that of a glossy or mottle-free film. *See* Mar. 30, 2012 Ex Parte Reexamination Interview Summary (prepared by Alan Diamond, a Patent Reexamination Specialist, and noting that "[t]he degree of uniformity of the instant film . . . was discussed relative of Chen and Strobush. Patent Owner argued and attempted to show that minimizing the formation of mottle as in Strobush doesn't necessary[il]y lead to uniform drug content in the film. Patent Owner argued that in the first 4 minutes of drying in the instant process, the drug particles are locked into place so as to obtain the uniformity. Patent Owner will consider adding claim language to specify the uniformity, such as *a film having no more than 10% variance of the drug particles per unit dosage*." (emphasis added)).[34]

[34] Plaintiff, in its opposition, attempts to distinguish between the language suggested at the interview and the final amended language. Specifically, Plaintiff argues as follows:

Finally, the comment accompanying the Notice of Intent to Issue Reexamined Patent notes at the outset that "[t]he compositional uniform distribution [of the amended claims] is measured by substantially equally sized individual doses which do not vary by more than 10% of the active component, which comprises drug particles" and states, in relevant part, that "Chen does not discuss compositional uniformity of an active component comprising drug particles. Table 4 of Chen gives the grams per dosage film and density . . . with standard deviation based on three or four measurements, but does not give compositional unity." Further, "Strobush provides no teaching with respect to compositional uniformity, and it is noted that . . . the films produced by the inventive process can often appear 'mottled' but also have a uniform distribution of active per unit dose."[35]

> During an interview, "[i]t was suggested by the Examiners to amend the claim to add 'uniformity of content per unit dose' of film as well as a maximum amount of variance of active content being no more than 10% or less of the targeted 100% Label Claim per unit dose." This language, quoted by Defendants, is different than the actual amendment. The amendment discusses 10% variation between dosage units, and not the "per unit dose."

Pl.'s Opp. Br. at 20. This argument is unavailing, because Plaintiff does not meaningfully distinguish variation between dosage units and variation per unit dose. Further, based on the prosecution history, it appears that both statements refer to the fact that the inventive process at issue provides for the uniform distribution of content throughout the film, resulting in variation of less than 10% of active content among dosage units. *Compare* Apr. 6, 2012 Summary of the Interview, at 4 ("the Patentee discussed controlling the rapid formation of the viscoelastic film in order to 'lock in' the active (i.e., drug) content during the drying process, thereby ensuring maintenance of the uniformity of content in the dried film, i.e., each unit dose of film, has substantially the same amount of active present.") *with* Apr. 6, 2012 Reply by Patentee to a Non-Final Office Action Pursuant to 37 C.F.R. § 1.111 (explaining that "the independent claims have been amended to recite that the compositional uniform distribution, i.e., the active content uniformity, is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component. Thus, . . . when unit doses are cut from the same film, each unit dose will contain substantially the same amount of active, and the variance of active of such unit doses is no more than 10%.").

[35] The Court also notes that the prosecution history reveals that initially, this amendment was only added to "certain of the independent claims," *see* Apr. 6, 2012 Reply by Patentee to a Non-

That this amendment had the effect of distinguishing over prior art, notably, Chen and Strobush, combined with the fact that the '292 patent's original claims were rejected upon reexamination due to being unpatentable over Chen and Strobush, among other prior art, is "highly influential" evidence demonstrating that the amendment was substantive. *Laitram IV*, 163 F.3d at 1348 ("Most significantly, . . . the addition of the 'type quality' limitation, along with the other amendments, resulted in the allowance of claims that had been rejected in the reexamination proceeding over prior art; this is a highly influential piece of prosecution history.").

Second, the amendment's language was not implicit in the claims as originally written. Plaintiff argues that "[t]he additional language is supported by the specification and merely states how a person of ordinary skill in the art would understand the original language." Pl.'s Opp. Br. at 18. Specifically, Plaintiff points to language in the specification stating that "[a] still further aspect of the present invention includes a pharmaceutical and/or cosmetic dosage form including a polymeric film having no more than a 10% variance of a pharmaceutical and/or cosmetic active per unit area." '292 Patent at Col. 6. Plaintiff further argues that "[i]n the pharmaceutical field, 10% variation of active ingredients is well understood" and, therefore, "a person with ordinary skill in the art would read the amendment as being consistent with the teachings of the specification." *Id.* In that regard, there is additional language in the specification stating that, "[c]urrently, by law, dosage forms may not vary more than 10% in the amount of active present. When applied to dosage units based on films, this virtually mandates that uniformity in the film be present." '292 Patent, Col. 2.

Final Office Action Pursuant to 37 C.F.R. § 1.111. However, the Examiner requested that the amendment be included in all of the independent claims. Supplemental Amendment Remarks, at 22 ("Claims 21–22 did not include a limitation regarding the measure of uniformity, and the Examiner requested the amendment be included."). This fact further demonstrates that this amendment was required to distinguish each independent claim over prior art.

However, while "claims 'must be read in view of the specification, of which they are a part,'" *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979), the case law is clear that "a court may not import limitations from the written description into the claims." *Laitram IV*, 163 F.3d at 1347.

> If everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment.

SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc) (citations omitted); *see also Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994) ("[A]lthough the specifications may well indicate that certain embodiments are preferred, particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments.").

Here, the specification's mention of no more than 10% variation in "a still further aspect" of the invention merely refers to a preferred embodiment of the claim. The specification describes numerous "aspects" of the invention, each encompassing a slightly different method of film formation. *See* '292 Patent, Cols. 3–6. The case law is in accord with this conclusion. *Altus Partners, LLC v. Globus Med., Inc.*, No. CIV.A. 13-822, 2013 WL 5803784, at *4 (E.D. Pa. Oct. 28, 2013) ("Statements in the specification describing 'one aspect of the present invention' are references to the preferred embodiment and are not claim limitations." (citing *Sandisk Corp. vs. Memorex Prods.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005))); *Flexhead Indus., Inc. v. Easyflex, Inc.*, No. CIV.A. 06-11898-DPW, 2008 WL 4813797, at *3 (D. Mass. Nov. 3, 2008). ("Statements describing 'one aspect' or 'another aspect' of the invention cannot reasonably be read to describe the invention 'as a whole.' They are more properly treated as embodiments of the invention. Embodiments described in the specification do not limit claim terms." (citing *Moore U.S.A., Inc.*

v. Standard Register Co., 229 F.3d 1091, 1111 (Fed. Cir. 2000), *cert. denied*, 532 U.S. 1008 (2001) (treating a reference in the patent to "one aspect of the present invention" as a preferred embodiment))); *see also, e.g.*, *Morningware, Inc. v. Hearthware Home Products, Inc.*, No. 09 C 4348, 2011 WL 1376920, at *5 (N.D. Ill. Apr. 12, 2011). Therefore, I find that the specification's description of a no more than 10% variance in a "still further aspect" of the invention to be contained in a preferred embodiment and, thus, that the description may not be imported into the claims. *Laitram IV*, 163 F.3d at 1247; *see also, e.g.*, *Flexhead Indus.*, 2008 WL 4813797, at *3.

Further, the specification's reference to "current law" has no relevance to the claims. The specification's reference reads in full as follows:

> Failure to achieve high degree of accuracy with respect to the amount of active ingredient in the cut film can be harmful to the patient. For this reason, dosage forms formed by processes such as Fuchs would not likely meet the stringent FDA standards relating to the variation of active in dosage forms. Currently, by law, dosage forms may not vary more than 10% in the amount of active present. When applied to dosage units based on films, this virtually mandates that uniformity in the film be present.

'292 Patent, Col. 2. I find that this part of the specification merely speculates about the possibility of meeting FDA guidelines; it does not imply that all embodiments of the '292 patent achieve such a maximum variance. Nor do I find that this section in the specification proves that an ordinary person skilled in the art would necessarily assume that the uniform distribution of the active component would mean a variation of no more than 10%.[36] Plaintiff's arguments that the

[36] Tellingly, the specification notes that a maximum 10% variation "virtually" mandates uniformity—it does not state that such a maximum variation precisely defines uniformity.

specification implies the amendment is unavailing;[37] therefore, I find that the amendment's language was not implicit in the '292 patent's original claims.[38]

Finally, the amendment constitutes a limitation because it surrenders territory. Specifically, the claims now exclude processes whereby the uniform distribution of a self supporting, edible film having a substantially uniform distribution of components, composed of (1) an edible water-soluble polymer component, (2) water, and (3) an active component comprising drug particles, is *not* measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component. *See Bloom Eng'g Co. v. N. Am. Mfg. Co.*, 129 F.3d 1247, 1251 (Fed. Cir. 1997) ("The amendment narrowed the claims to exclude an injected gas stream that includes combustion air, and to require a separate combustion air stream."); *see also, e.g.*, *Convolve, Inc. v. Compaq Computer Corp.*, 33 F. Supp. 3d 316, 342–43 (S.D.N.Y. 2014) ("Plaintiff here, having amended its claims to limit the patented method's application only to 'seek' acoustic noise, argues that the original claims were already implicitly limited to 'seek' noise. But the original claims

[37] Further, if the Court adopted Plaintiff's argument, it would render the added term superfluous. *See Merck & Company, Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."); *see also, e.g.*, *Scarborough v. Integricert, LLC*, No. CIV. 6:12-0396, 2015 WL 5099128, at *9 (W.D. La. Aug. 31, 2015).

[38] The Court notes that Plaintiff does not cite to any case law specifically applying its argument that the Court should read in the above language in the specification into the claims at issue here. *See generally* Pl.'s Opp. Br. As acknowledged by the Federal Circuit in *Laitram IV*, "it is difficult to conceive of many situations in which the scope of a rejected claim that became allowable when amended is not substantively changed by the amendment . . . ." 163 F.3d at 1348.

Moreover, to the extent Plaintiff points to self-serving statements in the prosecution history, made by the Patentee's attorney, for the proposition that this amendment was not necessary to distinguish over prior art, the Court disregards such statements. *See, e.g.*, *HTC Corp. v. Tech. Properties Ltd.*, No. 5:08-CV-00882-PSG, 2013 WL 5225043, at *9 (N.D. Cal. Sept. 17, 2013), *appeal dismissed* (Jan. 7, 2015) ("[T]he court should not credit self-serving testimony from the prosecution history.") (citing *Moleculon Research Crop. v. CBS, Inc.*, 793 F.2d 1261, 1270 (Fed. Cir. 1986)).

employ the term 'acoustic noise' with no modifier, which—by its plain language—covers situations where 'spindle' or other acoustic noise, as well as 'seek' acoustic noise, is targeted by the claimed method.") (internal citation omitted).

Therefore, I find that the phrase "whereby said compositional uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of active component" constitutes a substantive change to the '292 patent's independent claims, and, thus, that it also substantially changes the '292 patent's dependent claims.

b. "by rapidly increasing the viscosity of said film upon initiation of drying"

However, out of an abundance of caution, I will also proceed to analyze whether the amendment regarding the rapid increase of viscosity of the film—specifically, the addition of the phrase "by rapidly increasing the viscosity of said film upon initiation of drying"—also constitutes a substantial change. I find that it does.

As stated *supra*, the prosecution history demonstrates that the amendment had the effect of distinguishing over prior art. While Chen and Strobush both encompass methods for drying, neither method utilizes a rapid drying process at a high heat that rapidly forms a visco-elastic film and locks in the uniformity of the active component. Apr. 6, 2012 Summary of the Interview ("Whereas Strobush requires a very small change in the heat transfer rate over time, the inventive process requires a larger change in heat transfer rate starting from the initiation of the drying process, in order to rapidly form the visco-elastic film and 'lock-in' place the uniformly distributed active."); *see also* March 30, 2012 Examiner Interview Summary Record ("Patent Owner argued that in the first 4 minutes of the drying process, the drug particles are locked in to place so as to obtain the uniformity.").

In its Notice of Intent to Issue a Reexamination Certificate, the PTO noted that the amended claims had the effect of distinguishing among the drying processes utilized by the present inventive process, Chen, and Strobush. May 11, 2012 Notice of Intent to Issue a Reexamination Certificate, at 2 ("While Chen exemplifies drying at 9 minutes . . . it does so at 50 degrees C . . . and Chen does not discuss what happens within the first 4 minutes of drying . . . [T]he drying [taught by Chen] . . . resulted in a lower initial transfer rate, the wet film dried more slowly and was thereby subjected to mass transfer (flow) prior to locking in the desired content of active per unit dose area." Meanwhile, "Strobush . . . desires to keep its heat transfer rate . . . below a threshold value to prevent mottle."). I find this fact "highly influential" and that it weighs heavily in favor of finding that a substantive change occurred. *Laitram IV*, 163 F.3d at 1348.

Further, I find that the amendment is not implicit. Plaintiff argues that "[t]he amended language merely describes what happens in the originally claimed drying step." Pl.'s Opp. Br. at 15. However, while the claims themselves state that the visco-elastic film is formed "by applying hot air current at temperatures of about 60° C. to about 100° C. to said bottom side of said surface with substantially no top air flow to prevent flow migration and intermolecular forces from creating aggregates or conglomerates of said drug particles thereby maintaining the compositional uniform distribution of components," the claims do not necessarily imply that the initiation of this heating process rapidly increases the visco-elasticity of the film to "lock-in" the placement of the drug particles. Nor can this fact be implied from the specification; rather, in describing the drying process, the specification merely states, in relevant part:

> The drying step can also be a contributing factor with regard to maintaining the uniformity of the film composition. A controlled drying process is particularly important when, in the absence of a viscosity increasing composition or a composition in which the viscosity is controlled, for example by the selection of the polymer, the components within the film may have an increased tendency to aggregate or conglomerate . . . . An alternative method of forming a film with an accurate dosage,

> that would not necessitate the controlled drying process, would be to cast the films on a predetermined well . . . . When a controlled or rapid drying process is desired, this may be through a variety of methods. A variety of methods may be used including those that require the application of heat . . . .

'292 Patent, at Col. 16–17. While the specification mentions that the drying process may have an impact on the distribution of the active component, it merely discusses various preferred embodiments of the invention which utilize different drying methods, only some of which even require the application of heat. *See Laitram IV*, 163 F.3d at 1348. Finally, I find that this amendment constitutes a limitation, because it excludes pharmaceutical film drying processes that otherwise conform to the claims as written but which do not "rapidly increase the viscosity of said film upon the initiation of drying." *See Bloom*, 129 F.3d at 1251. Therefore, I find that the amendment "by rapidly increasing the viscosity of said film upon the initiation of drying" to constitute a substantive change to the '292 patent.

Therefore, I find that at least two of the amendments made to the '292 patent's independent claims (and, by incorporation, its independent claims)[39] upon reexamination constitute substantive changes. I find that Defendants are entitled to absolute intervening rights, and, thus, are not liable for infringing upon the '292 patent prior to July 3, 2012, the date that the PTO issued its reexamination certificate for the patent. Accordingly, summary judgment is granted to Defendants on Plaintiff's patent infringement claim as to the '292 patent.[40]

b. '891 Patent

[39] "As stated in 35 U.S.C. § 112 ¶ 4, a dependent claim incorporates by reference all of the limitations of the claim from which it depends." *Bloom*, 129 F.3d at 1250.

[40] Because I find that the above-discussed amendments are substantive, I need not reach the question of whether the amendments "including said active component" and "said active component comprising" also constitute substantive changes. *See, e.g.*, *Eberle*, 2010 WL 6281563.

I next turn to whether the '891 patent was substantively changed upon reexamination. While the patent's original nine claims were cancelled, the two independent claims what were added, claims 10 and 11, appear to be identical to the cancelled claims 1 and 7, except the following phrase was added to both claims: "wherein said desired level is measured by substantially equially-sized [sic] individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active component." The added phrase modifies the existing phrase "wherein said pharmaceutical or biological active component is maintained at said desired level."[41] I find that, for the following reasons, this phrase indeed constitutes a substantive change over claims 1 and 7 as originally written. Thus, Defendants are also entitled to absolute intervening rights as to the '891 patent.

First, the prosecution history reveals that this amendment to original claims 1 and 7 had the effect of distinguishing the '891 patent over prior art. Claims 1 and 7, both processes "for making an ingestible film having a substantially uniform distribution of components and a desired level of a pharmaceutical or biological active component," were cancelled because they were unpatentable over prior art. Specifically, Claim 1 was unpatentable because, according to the PTO,

> [i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the drying method taught by Strobush to the film formation disclosed by Chen to achieve uniformity in density of the active component. In particular, in order to achieve uniformity in density of the active component in Chen's dried film[,] it would have been obvious to one of ordinary skill in the art at the time the invention was made to dry Chen's film in, for example, three zones as in Strobush so as to dry the film such that it is virtually mottle proof in the first zone and then remove remaining water in the subsequent two zones.

March 1, 2012 Office Action in Ex Parte Reexamination, at 8–9. Further,

> [i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized Chen's drying step by using as high a drying

[41] *See supra* note 31 (explaining that the Court will examine whether claims 10 and 11 are substantial changes over the '891 patent's original claims 1 and 7).

> temperature as possible with Chen's disclosed [sic] the range of 40-100C without destabilizing the protein theraputive agent . . . because temperature is a results-effective variable with respect to active agent destabilization as taught by Chen; and so as to dry Chen's film as quickly as possible.

Id. at 10. Claim 7 was rejected because "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared Chen's premix in one mixing vessel, then transferred it to another vessel of a cooler temperature, and then stirred in heat sensitive active ingredients such as proteins because such is conventional processing in the art and so as to avoid degradation of the heat sensitive materials." *Id.* at 11. Further, "[i]n order to achieve uniformity in density of the active component in Chen's dried film[,] it would have been obvious to one of ordinary skill in the art at the time the invention was made to dry Chen's film in, for example, three zones as in Strobush as discussed above, and determine the appropriate parameters, including time, for each zone, so as to dry the film such that it is virtually mottle proof in the first zone and then remove remaining water in the subsequent two zones." *Id.* 12.

In an interview held between the Examiners, the Patentee's representative, and MonoSol representatives, which was summarized by Daniel A. Scola, attorney for the patentee, "[t]he Patentee and the Examiners discussed various amendments that may be included in the claims. In particular, the Patentee and the Examiners discussed clarifying the 'desired level' of active in the claims as being measured by 'substantially equally-sized individual unit does which do not vary by more than 10% of said pharmaceutical or biological active component." May 1, 2012 Summary of the Interview, at 3.

In the PTO's comments accompanying the July 7, 2012 Notice of Intent to Issue Ex Parte Reexamination Certificate as to the amended '891 patent, the PTO noted that "Chen does not discuss uniformity or pharmaceutical or biological active component in its doses. Table 4 of Chen gives the grams per dosage film and density for Example 1 with standard deviation based on three

or four measurements, but does not give compositional uniformity," and that "Strobush provides no teaching with respect to compositional uniformity."[42] Defs.' Stmt. of Facts ¶ 51 (quoting July 6, 2012 Reasons For Patentability).[43] Thus, as in the amended '292 patent, the fact that this amendment had the effect of distinguishing over prior art, notably, Chen and Strobush, combined with the fact that the '891 patent's original claims were rejected upon reexamination due to being unpatentable over Chen and Strobush, is "highly influential" evidence demonstrating that the amendment was substantive. *Laitram IV*, 163 F.3d at 1348.

Second, this amendment was not implicit in the original claims. Indeed, the mere fact that claims 1 and 7 were rejected as unpatentable, and that the approved claims 10 and 11 track the language of claims 1 and 7, except for the amended language, suggests that the original language did not inherently contain the amendment at issue. *Cf. Yoon Ja Kim v. Earthgrains Co.*, 451 Fed. App'x 922, 925 (Fed. Cir. 2011) ("Why, if the claims are of identical scope, did [the patentee] amend them?"). Plaintiff argues that this limitation is present in the specification and should thus be read into the claims. In the "Background of the Related Technology" section of the specification, it is stated that "Currently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present. When applied to dosage units based on films, this virtually mandates that uniformity in the film be present." *Id.* Col. 2. This language is strikingly similar to the language used in the '292 patent's specification as to the FDA

[42] Further, the PTO noted that "Staab is [also] silent with respect to dosage uniformity . . . ." *Id.*

[43] To the extent Plaintiff points to self-serving statements in the prosecution history, made by the Patentee's attorney, for the proposition that this amendment was not necessary to distinguish over prior art, the Court disregards such statements. *See supra* note 38.

standard for dosage forms. *Compare id. with* '292 Patent, Col. 2. Further, in the "Detailed Description of the Invention" section, the specification states the following:

> Consideration of the above discussed parameters, such as but not limited to rheology properties, viscosity, mixing method, casting method and drying method, also impact material selection for the different components of the present invention. Furthermore, such consideration with proper material selection provides the compositions of the present invention, including a pharmaceutical and/or cosmetic dosage form or film product having no more than a 10% variance of a pharmaceutical and/or cosmetic active per unit area. In other words, the uniformity of the present invention is determined by the presence of no more than a 10% by weight of pharmaceutical and/or cosmetic variance throughout the matrix. Desirably, the variance is less than 5% by weight, less than 2% by weight, less than 1% by weight, or less than 0.5% by weight.

'891 Patent, Col. 14.

This Court found *supra* that the '292 patent's reference to FDA dosage uniformity standards should not be read in to that patent's claim language on uniformity. Likewise, I find that the '891 patent's reference to world regulatory dosage requirements should not be read into measuring the uniformity of the desired levels of active component in that patent's claims. The specification language merely generally comments on the possibility of obtaining regulatory approval to someday market any medicines developed using its method. It does not demonstrate that an ordinary person skilled in the art would necessarily understand that the desired level of active component mentioned in the '891 patent's claims would be measured by equally sized dosage units which do not vary by more than 10% of the active component.

As to the specification's other language about a no more than 10% variance in the amount of active present, I find that Plaintiff is requesting the Court to read in the above limitation from the specification into the claim, which is impermissible. *Laitram IV*, 163 F.3d at 1347. The specification defines *uniformity* of the present invention as "determined by the presence of no more than a 10% by weight of the pharmaceutical and/or cosmetic variance throughout the matrix." '891 Patent, Col. 11. However, the original claims merely describe a "process for making an ingestible

film having a *substantially* uniform distribution of components and a desired level of a pharmaceutical or biological active component." '292 Patent, Claim 1; *see also* Claim 7 (emphasis added). As the Federal Circuit has recognized, "the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter, ...'" *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001); *see also Dana Corp. v. Am. Axle & Mfg., Inc.*, 110 Fed. App'x 871, 876 (Fed. Cir. 2004). In *Ecolab*, which involved an invention for a solid detergent cast, the Federal Circuit found in relevant part that (1) "no basis exists for inferring a numerical limitation as to what is a 'substantially uniform' cast," and (2) "'substantially' avoids the strict 100% nonuniformity boundary.'" 264 F.3d at 1365–67. I find similarly in this case. Specifically, here, (1) the term "substantially uniform" is a non-numerical limitation, and (2) a measure of "uniformity" would not necessarily capture a distribution of active component that was merely "substantially uniform." As the Patentee described it in the prosecution history, the amendment "clarifies that the active component is maintained in a known and useful amount," thus distinugishing over prior art in which the active component varies more across dosage units. May 1, 2012 Reply by Patentee to a Non-Final Office Action Pursuant to 37 C.F.R. § 1.111, at 19. This clarification is otherwise absent in the claims as originally written; therefore, the amendment was not implicit.[44]

Third, the amendment constitutes a limitation. As explained *supra*, the phrase "wherein said desired level is measured by substantially equally-sized individual unit doses which do not vary

[44] Further, if the Court adopted Plaintiff's argument, it would render the added term superfluous. *See Merck*, 395 F.3d at 1372; *see also supra* note 37.

Finally, as with its argument as to the '292 patent amendments, Plaintiff does not cite to any case law specifically applying its argument that the Court should read in the above language in the specification into the claims at issue here. *See generally* Pl.'s Opp. Br.

by more than 10% of said pharmaceutical or biological active component" narrows the scope of the "desired level" of the pharmaceutical or biological active component by excluding levels that vary by more than 10% of the pharmaceutical or biological active component. *See Bloom*, 129 F.3d at 1251; *see also, e.g.*, *Convolve*, 33 F. Supp. 3d at 342–43.

Therefore, I find that the phrase "wherein said desired level is measured by substantially equially-sized [sic] individual unit doses which do not vary by more than 10% of said pharmaceutical or biological active component," as included in independent claims 10 and 11 of the '891 patent upon reexamination, constitutes a substantive change to independent claims 1 and 7 of the patent, which claims 10 and 11 replaced. Thus, I find that the amendment also substantially changes the '891 patent's dependent claims.[45] As such, I find that Defendants are entitled to absolute intervening rights, and, thus, are not liable for infringing upon the '891 patent prior to August 21, 2012, the date that the PTO issued its reexamination certificate for the '891 patent. *See* '891 Patent Ex Parte Reexamination Certificate. Accordingly, summary judgment is granted to Defendants on Plaintiff's patent infringement claim as to the '891 patent.

IV. Conclusion

For the foregoing reasons, Defendants' motion for summary judgment is granted.[46] An appropriate order shall follow.

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[45] *See supra* note 39 (explaining that a dependent claim incorporates all of the limitations of the independent claim upon which it is based).

[46] The third patent on which Plaintiff asserted patent infringement claims, the '588 patent, was cancelled in its entirety upon reexamination. '588 Patent Ex Parte Reexamination Certificate. Therefore, Plaintiff's patent infringement claims as to the '588 patent are dismissed. *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330, 1346 (Fed. Cir. 2013) ("[I]t could hardly be clearer that Congress meant for cancellation to terminate pending [patent infringement] suits. When it amended the pertinent statutory language in 1928, Congress acknowledged that cancelled claims were void *ab initio*."). In a footnote in its opposition brief, Plaintiff agrees, acknowledging that

Dated: September 25, 2015

/s The Honorable Freda L. Wolfson
United States District Judge

"[a]ll claims of the '588 patent have been . . . cancelled, and it is therefore no longer a part of the case." Pl.'s Opp. Br. at 3 n.1.